IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

JENNIFER R. COKER, Plaintiff, v. C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	Civil Action No. 1:13-CV-00515-TWT

DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF BARD'S INTERNAL RATES BASED UPON REPORTING RATES OF FILTER COMPLICATIONS

Plaintiff's Motion is essentially a refiled copy of a three-year-old brief that Judge Campbell denied in the Bard IVC Filter MDL, *In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-00263-PHX-DGC, 2019 WL 1880029, at *2–3 (D. Ariz. Apr. 26, 2019).[1] Plaintiff fails to inform this Court of that ruling, nor does she make any attempt to distinguish it. Instead, she ignores it all together. Plaintiff also ignores the fact that evidence of Bard's internally calculated reporting rates (including the rates chart identified as Defs.' Trial Exhibit 82 in this case) was admitted during

[1] *Cf.* **Ex. A**, Pls.' Motion in *Limine*, *In re Bard IVC Filters Prods. Liab. Litig.*, Case 2:15-md-02641-DGC, Doc. 16579 (D. Ariz. Mar. 29, 2019).

every MDL bellwether trial over the MDL plaintiffs' hearsay and Rule 403 objections (the same objections Plaintiff raises here) including in the first two bellwether trials (*Booker* and *Jones*) that involved failure to warn and punitive damages claims under Georgia law.[2] Further, Bard's internal rates evidence was admitted in every other Bard IVC Filter remand case tried to date, including three cases involving the Recovery Filter.[3] This highly relevant evidence is equally

[2] *See, e.g.*, **Ex. B**, Trial Tr. at 2349:16–2351:8, *Booker v. C. R. Bard, Inc.*, MD-15-02641-PHX-DGC (D. Ariz. Mar. 2018) ("*Booker* Trial Tr.") (admitting over MDL plaintiff's hearsay objection Trial Exhibit 5874, which is Bard's reported rate chart).

[3] *See, e.g.*, *Laloli v. C.R. Bard, Inc.*, No. 19-CV-05679-JST, 2021 WL 3141190, at *1 (N.D. Cal. July 25, 2021) ("To the extent the motion seeks to preclude evidence of Bard's reported complication rates – whether internal, external, or otherwise – the motion is denied."); *accord Ocasio* v. *C. R. Bard, Inc.*, No. 8:13-CV-1962-CEH-AEP, 2021 WL 2787993, at *5 (M.D. Fla. July 5, 2021); *Johnson v. C.R. Bard Inc.*, No. 19-CV-760-WMC, 2021 WL 2070448, at *9 (W.D. Wis. May 24, 2021) (holding "this evidence appears central to the dispute in this case -- namely, whether the [Bard IVC] Filter was unreasonably dangerous, whether its warnings were adequate, and whether the benefits of the device outweigh its risks. If anything, plaintiff's objection goes to the weight, not the admissibility, of this evidence, and her motion will be DENIED."); **Ex. C**, Pretrial Conf. Tr. 18:11–19:21, *Peterson v. C. R. Bard, Inc.*, No. 3:19-cv-01701-MO, Doc. 161 (D. Or. April 20, 2021); **Ex. D**, Civil Minutes, *Peterson v. C. R. Bard, Inc.*, Case No. 3:19-cv-01701-MO, Doc. 159 (D. Or. April 21, 2021) (granting and denying in part similar motion in limine [7], as stated on the record); **Ex. E**, Order at 3, *Nolen v. C. R. Bard, Inc., et al.*, No. 3:19-cv-00799, Doc. 183 (M.D. Tenn. May 26, 2021) (granting and denying in part similar motion *in limine*, "as this information is relevant in many respects, and any defects in its internal processes can be explored by the plaintiff on cross-examination.").

admissible in this case for the reasons below, and this Court should deny Plaintiff's Motion.

I. ARGUMENT AND CITATION OF AUTHORITY

A. Bard's Internal Reported Complication Rates Are Highly Relevant and Trustworthy.

Plaintiff does not dispute the relevance of Bard's reported complication rates. They go directly to the heart of the issues in this case: whether Bard acted reasonably in providing warnings of the risks of the Recovery Filter, whether its warnings are adequate, and whether its reported failure rates are within those accepted as reasonable by the medical community. This evidence also goes directly to whether Bard acted with conscious indifference to the consequences as Plaintiff alleges. Indeed, one of Plaintiff's central claims in this case is that the Recovery Filter causes higher rates of complication than other IVC filters—including Bard's Simon Nitinol Filter ("SNF")—and, thus, Bard's warnings were inadequate, and its actions in warning about the risks of the Recovery were not reasonable and warrant punitive damages. (*See, e.g.*, Doc. 162 at 5; Doc. 140-4 at 11-12, 14, 16 (basing her claims on purported higher complication rates); Doc. 96 at 1, 6-17, 22 (same); *e.g.*, *id.* at 13-14 ("[The Recovery IFU] provided no failure rates—rates that doctors would have found unacceptable, and failed to warn that Bard's IVC filters tilt, migrate, and fracture at rates higher than competitor filters and Bard's SNF."); *id.* at 12 (arguing

"Plaintiffs survive summary judgment by showing that the Recovery filter fractured at rates higher than that accepted by doctors.").)

Instead, Plaintiff raises concerns with the quality of Bard's data. But Bard has been fully candid in explaining what its reporting rates are, and what they are not. Bard's former VP for Quality, Mr. Chad Modra, testified that Bard's calculation of reported IVC filter complication rates is based on the number of reported complaints that Bard uncovers and identifies from multiple sources—which Bard documents in a database called "Trackwise," (*see* **Ex. B**, *Booker* Trial Tr. 2341:2-8; 2348:12-16)—and Bard's sales data. (*Id.* at 2341:14-20.)[4] Bard anticipates Mr. Modra—or another witness with knowledge—will testify regarding these matters during the trial of this case. Bard recognizes its internally calculated ***reporting rates*** do not constitute the precise complication rates. (*Id.* at 2352:8-10.) But whether a certain percentage of IVC filter complaints are underreported, as Plaintiff alleges, is of no moment. Bard recognizes some degree of underreporting may exist, (*id.* at 2352:25-

[4] Plaintiff's argument that "there is no way to substantiate the rates in the chart" is unavailing. As Plaintiff should know from the MDL proceedings and the briefing on this identical motion, Bard produced the contents of its Trackwise database and its internal sales figures years ago. Moreover, contrary to Plaintiff's argument and consistent with Judge Campbell's ruling in the MDL, Bard will not use the reporting rates to claim Recovery Filters are "99.9% effective." *In re Bard IVC Filters*, 2019 WL 1880029, at *3 n.2.

2353:6), and does everything possible to minimize the impact by aggressively investigating all reports of potential complications. Its internal calculations reflect the rates of reported complications based on that robust process, and do not purport to reflect the actual complication rate with absolute certitude. (*Id.* at 2347:22–2348:8.)

Mr. Modra's testimony confirms the trustworthiness of the data.[5] Bard routinely monitors, tracks, and trends product complication rates, including updating reported rate information on a monthly basis, (*id.* at 2340:4–7), and can calculate reported rates at any point. (*Id.* at 2341:2-20.) These activities are conducted pursuant to Bard's internal standard operating procedures (*id.* at 2335:19 - 2336:5; 2338:8 - 2340:7; 2349:4-11), and Bard relies on the reported rate calculations when making product risk assessments. (*Id.* at 2259:8–16.) Moreover, Bard has a substantial interest in ensuring the accuracy of its reported rate calculations, given Bard is required under federal regulations to keep and maintain quality system

[5] Plaintiff argues FDA found in the Warning Letter that Bard underreported adverse events. (*See* Doc. 162 at 3.) As explained in Bard's Motion *in Limine* to Exclude the FDA Warning Letter, the Letter did not address the Recovery Filter at all, and FDA's allegations in the Letter do not impact the accuracy or reliability of Bard's reported rate calculations. (*See* Doc. 148; **Ex. B**, *Booker* Trial Tr. 2326:1-2327:2.) At most, Plaintiff's erroneous argument—even if valid—would be a topic for cross-examination, not exclusion of Bard's highly relevant reported rates evidence.

records and to "evaluat[e] complaints by a formally designated unit." 21 C.F.R. § 820.198(a).

Plaintiff claims Bard's reported rate calculations are unreliable because the numbers on Bard's charts do not match the "over 4,000 cases that were in the MDL" who have filed cases against Bard. (Doc. 162 at 3.) Again, Plaintiff ignores that Judge Campbell denied this identical argument in the MDL and admitted this very evidence in every MDL bellwether trial. Regardless, Plaintiff fails to note the rate chart contains data involving 2,959 patients through the end of 2016, when fact discovery in the MDL was nearing completion. Bard's calculations included all complications reported in lawsuits as of that date (to the extent they alleged one of the failure modes identified). Data that included all MDL complaints would be less reliable because the rates would be based entirely on the characterization of the complications by the MDL plaintiffs' attorneys. Bard identified this same December 2016 rates chart as a trial exhibit in this case because Plaintiff's trial counsel is familiar with it from the MDL bellwether trials and thus had fair notice of those rates. If Plaintiff takes issue with the timing of this data, Bard is willing to substitute this December 2016 chart (Defs.' Trial Exhibit 82) with a chart of rates through

January 2013, which would include all rates of complications reported before Plaintiff filed suit in February 2013.[6]

Further, Bard recognizes the number of IVC filters it has sold is not the same number of IVC filters implanted in patients, and Bard will not represent the same to the jury. Mr. Modra's prior testimony is clear that not all IVC filters sold are actually implanted. (*See* **Ex. B**, *Booker* Trial Tr. 2352:11-13.). But, as Mr. Modra explains, given the relative price of Bard's filters, the large majority of filters sold are likely implanted. (*Id.* at 2352:14–24.) Also, Bard uses the number of filters sold as the "denominator" to calculate its reported complication rates, as discussed above (*id.* at 2341:14–20).

[6] Plaintiff's cursory request in a footnote to be able to offer summaries of "all legal complaints," "internal complaint files," and "MAUDE data," to counter this evidence should be denied. (Doc. 162 at 4 n.1) Even if this copied request was made in good faith, for the same reasons as explained in Bard's Motion in *Limine* to Exclude Evidence Regarding Recovery Filter Migration Deaths, Plaintiff would need to first demonstrate "substantial similarity" between her experience with her Recovery Filter and those of the thousands of other patients with any Bard IVC filter before this evidence could be admissible, which she cannot do. (*See* Doc. 150 at 11–14.) And even if she could, its minimal probative value would be cumulative of Plaintiff's statistical expert and would be substantially outweighed by the danger of confusing the issues, misleading the jury, and unfairly prejudicing Bard under Rule 403. Again, Judge Campbell denied an identical motion with this identical footnoted request. *See In re Bard IVC Filters*, 2019 WL 1880029, at *3. This Court should too.

Bard's internally calculated reported rates for the Recovery Filter are highly probative evidence that Bard will present in appropriate context. Given the clear relevance of the evidence, Plaintiff's Rule 403 arguments regarding the quality of the data are best reserved for cross examination.

II. CONCLUSION

For these reasons, Bard requests that this Court deny Plaintiff's Motion.

Dated May 10, 2022.

Respectfully submitted,

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Certificate of Compliance

In accordance with Local Rule 7.1D, this is to certify that this brief has been prepared with one of the fonts and points approved by the Court in LR 5.1B, i.e., 14 point, Times New Roman font, and that the brief does not contain more than 10 characters per inch of type.

This 10th day of May, 2022.

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